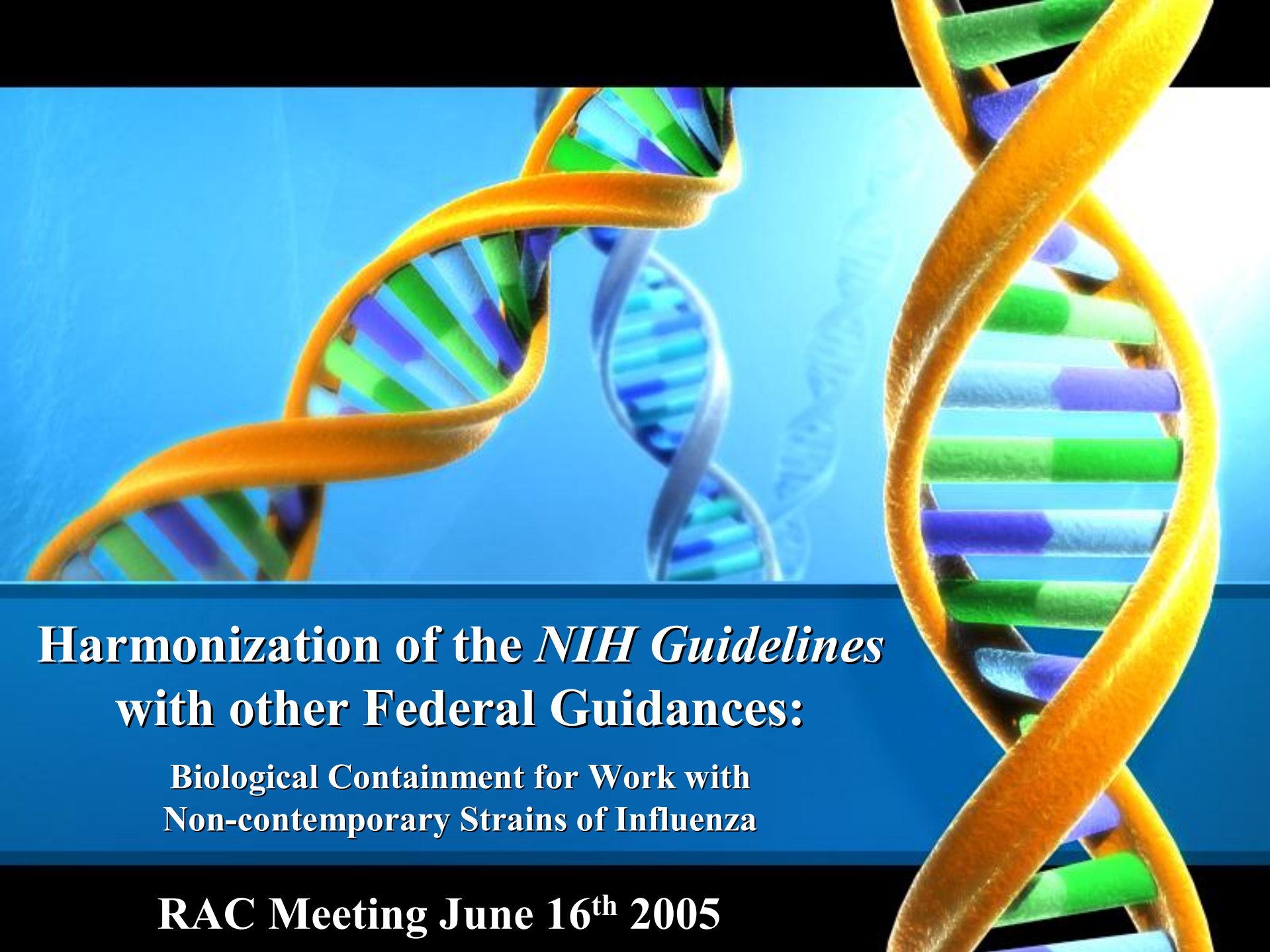


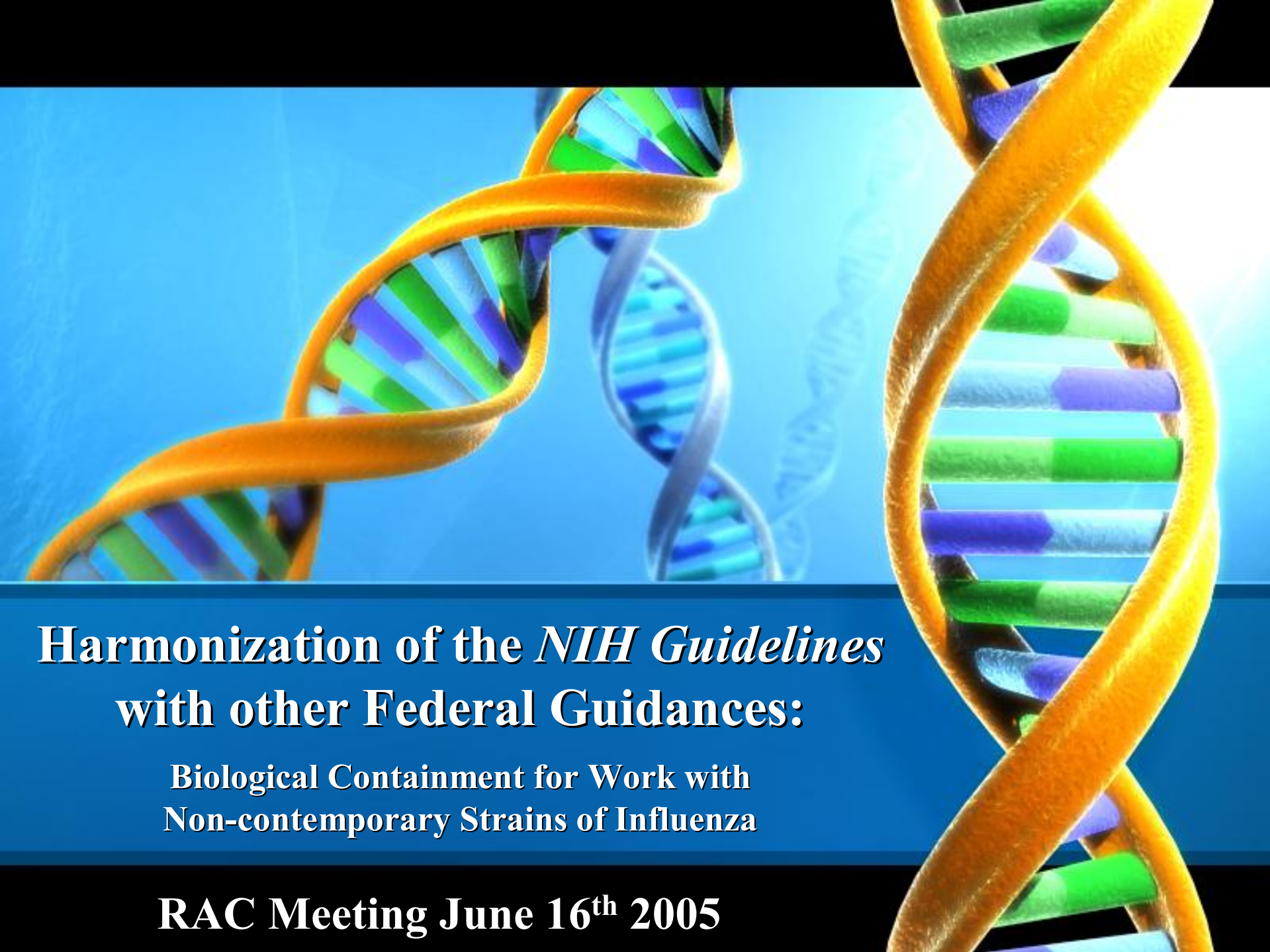
Harmonization of the *NIH Guidelines* with other Federal Guidances:

Biological Containment for Work with Non-contemporary Strains of Influenza

RAC Meeting June 16th 2005

Jacqueline M. Katz, Ph.D.

Chief of the Immunology and Viral Pathogenesis Section,
Influenza Branch, Division of Viral and Rickettsial Diseases,
National Center for Infectious Diseases,
Centers for Disease Control and Prevention, Atlanta, Ga.



Harmonization of the *NIH Guidelines* with other Federal Guidances:

Biological Containment for Work with Non-contemporary Strains of Influenza

RAC Meeting June 16th 2005

Risk Groups and Containment Levels

- **Risk Groups**

RG1	**Agents are not associated with disease in healthy adult humans.**
RG2	**Agents are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are *often* available.**
RG3	**Agents are associated with serious or lethal human disease for which preventive or therapeutic interventions *may be* available.**
RG4	**Agents are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are *not usually* available.**

- **Containment levels**
  - **Containment level often equivalent to the Risk Group**
  - **Containment level may be raised or lowered depending on a comprehensive risk assessment.**

Current Recommendations

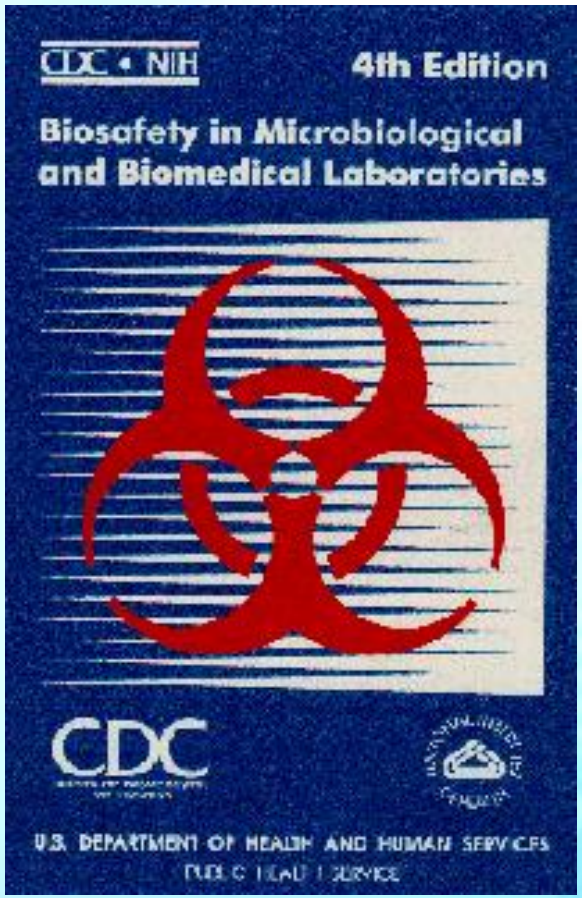
- **Appendix B-II-D. Risk Group 2 (RG2) – Viruses**
  - **Orthomyxoviruses**
    - **Influenza viruses types A, B, and C**
    - **Other tick-borne orthomyxoviruses as listed in the reference source (see Section V-C, *Footnotes and References of Sections I through IV*)**
- **Containment levels higher than the Risk Group classification may be appropriate.**
  - **Biosafety Level 3 containment is appropriate for research with non-contemporary strains.**

New Recommendations

- **May 3, 2005 - CDC announced an increase in the recommended containment level (from Biosafety Level 2 to Biosafety Level 3) for laboratories working with non-contemporary strains.**
  - **Pandemic potential**
  - **Lab worker and public safety**

New Recommendations

- **Fall 2005 - CDC/NIH publication *Biosafety in Microbiological and Biomedical Laboratories* (5th Edition) will recommend a similar increase in containment level for:**
  - **Non-contemporary human influenza strains**
  - **Research involving reverse genetics of the 1918 influenza strain**
  - **Highly Pathogenic Avian Influenza (H5N1).**



Next Steps

- **Specify that the Risk Group classification for non-contemporary strains of Orthomyxoviruses (including H2N2, H5N1 Highly Pathogenic Avian Influenza virus, and 1918 Influenza virus) is Risk Group 3.**
- **Provide additional specific biosafety recommendations for research with non-contemporary strains of Orthomyxoviruses, in keeping with the recently publicized CDC recommendation and the revised language for the 5th edition of the BMBL.**

(Contemporary strains of Orthomyxoviruses will retain their classification as Risk Group 2 agents)

Change to Appendix B-II-D Risk Group 2 (RG2) – Viruses

Proposed Change to Existing Text:

Orthomyxoviruses

- **Influenza viruses types A, B, and C except non-contemporary human strains (including H2N2 and 1918 Influenza virus), and highly pathogenic avian influenza virus (H5N1), (see Appendix B-III-D, Risk Group 3 (RG3) – Viruses and Prions)**
- **Other tick-borne orthomyxoviruses as listed in the reference source (see Section V-C, *Footnotes and References of Sections I through IV*)**

Change to Appendix B-II-D
Risk Group 3 (RG3) – Viruses and Prions

Text To Be Added:

Orthomyxoviruses

- **Non-contemporary human strains of influenza viruses (including H2N2 and 1918 Influenza virus) and highly pathogenic avian influenza virus (H5N1).**

Change to Section II-A-3 Comprehensive Risk Assessment

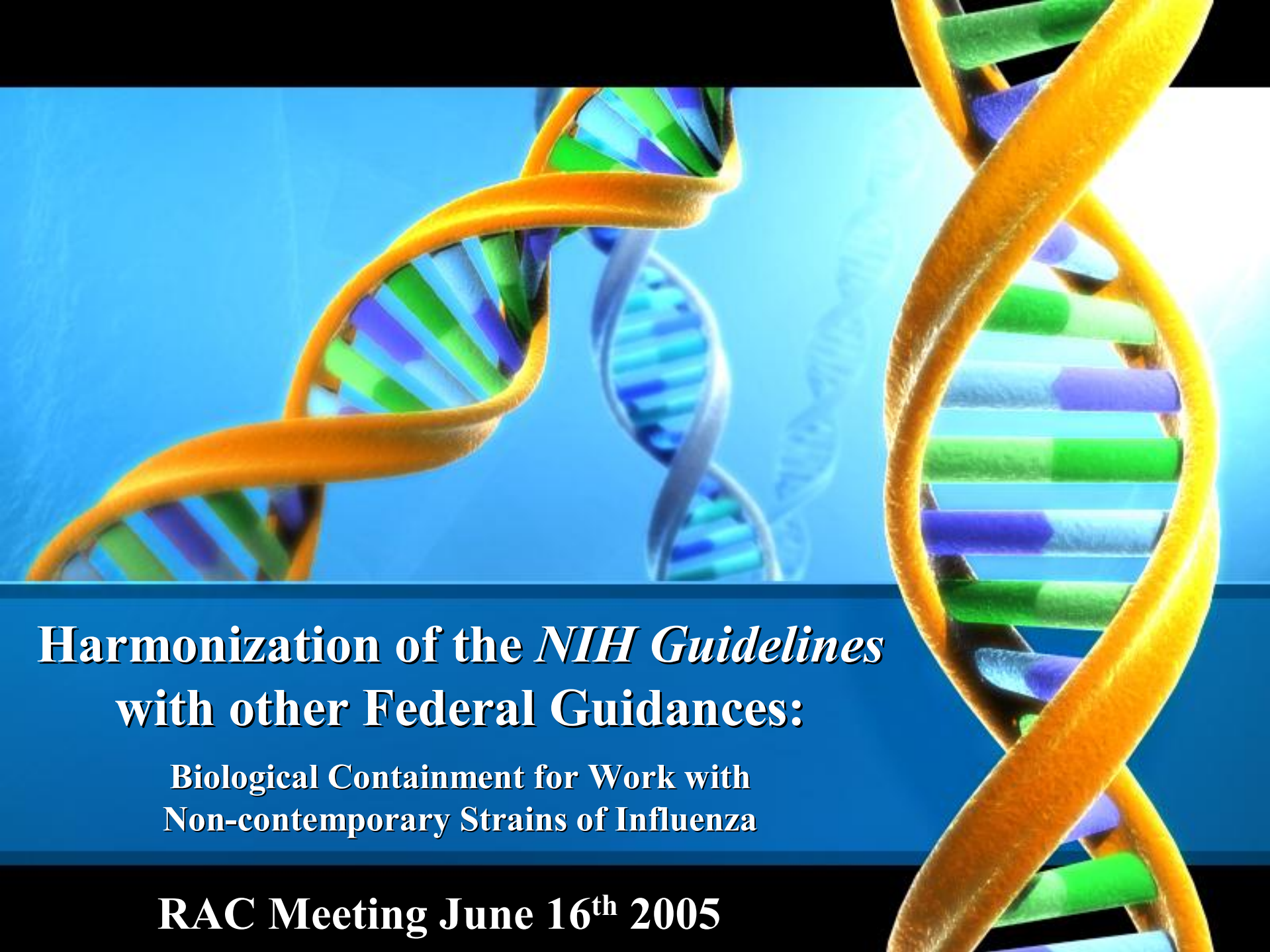
- **Important considerations**
  - **Number of years since an antigenically related virus last circulated**
  - **Potential for presence of a susceptible population**
  - **Significant pandemic potential**
  - **Significant agricultural and economic implications.**
  - **Availability of risk assessment data**

Addition to Section II-A-3 Comprehensive Risk Assessment

- Biosafety Level 3 and Animal Biosafety Level 3 practices, procedures and facilities
- Large laboratory animals such as nonhuman primates should be housed in primary barrier systems in ABSL-3
- Rigorous adherence to additional respiratory protection and clothing change protocols
- Use of negative pressure, HEPA-filtered respirators or positive air-purifying respirators (PAPRS)
- Use of HEPA filtration for treatment of exhaust air
- Amendment of personnel practices to include personal showers prior to exiting the laboratory.

Summary

- **The NIH will be revising the *NIH Guidelines* classification of non-contemporary strains of influenza to reflect new guidance from the CDC regarding the recommended containment for these agents.**
  - **The classification for non-contemporary strains of Influenza in Appendix B of the *NIH Guidelines* will be Risk Group 3**
  - **Specific biosafety recommendations for research with non-contemporary strains of Influenza will be added to Section II-A-3 of the *NIH Guidelines***
  - **Contemporary strains of Influenza will retain their classification as Risk Group 2 agents**



Harmonization of the *NIH Guidelines* with other Federal Guidances:

Biological Containment for Work with Non-contemporary Strains of Influenza

RAC Meeting June 16th 2005

HPAI

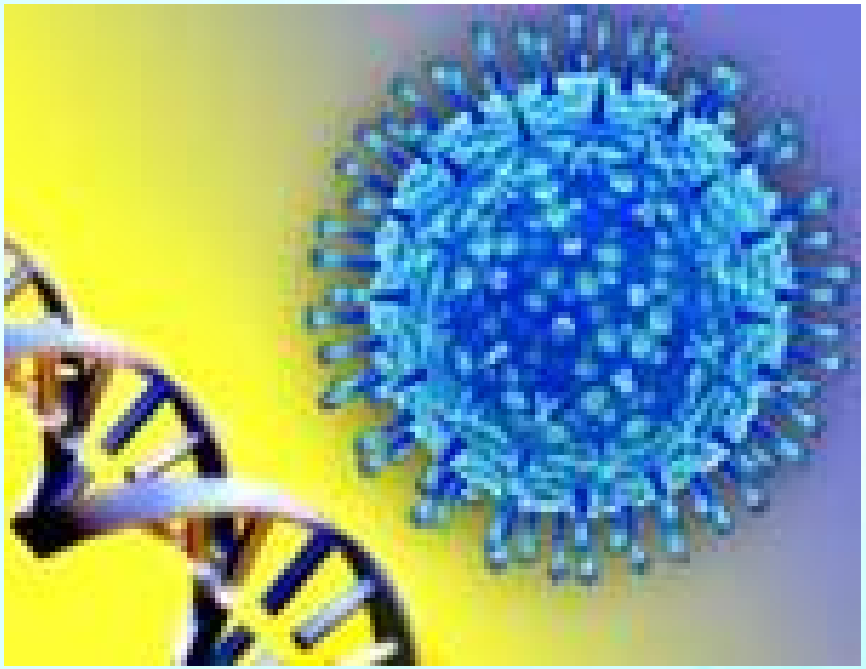
- The definition of Highly Pathogenic Avian Influenza (HPAI):
  - Any influenza virus that kills at least 75% of eight 4 to 6 to week-old chicks within 10 days of inoculation with a 1:10 dilution of infectious allantoic fluid;
  - Any H5 or H7 that does not meet the criteria above but has an amino acid sequence at the hemagglutinin cleavage site that is compatible with HPAI; or
  - Any influenza virus that is not an H7 or H5 and kills one to five chickens and grows in cell culture in the absence of trypsin.

Resources

Fourth National NIH Safety Symposium

Safety Considerations in Recombinant DNA Research with Pathogenic Viruses

September 21-22, 2004



www4.od.nih.gov/oba/RAC/SSSept04/resources.htm